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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,688	09/27/2001	Seishi Kato	2001-1102A	6753

513 7590 11/28/2003

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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,688	KATO ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *1,7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. This action is in response to Applicant's response filed on August 15, 2003. Currently, claims 1-9 are pending.

Election/Restrictions

2. Applicant has correctly stated that the instant application should have been subject to unity of invention restriction practice. Accordingly, the previous restriction is withdrawn in view of the restriction set forth herein.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups 1-80, claim(s) 1, drawn to a purified human protein. Group 1 is drawn to claim 1, SEQ ID NO: 2; Group 2 is drawn to claim 1, SEQ ID NO: 4, etc.

Groups 81-160, claim(s) 2-6 and 8, drawn to DNA fragments and expression vectors capable of expressing said DNA fragments. Group 81 is drawn to claims 2-6 and 8, with respect to SEQ ID NO:1; Group 82 is drawn to claims 2-6 and 8, with respect to SEQ ID NO: 3, etc.

Group 161, claim(s) 7, drawn to fluorescent protein-fused protein.

Groups 162-241, claim 9, drawn to an antibody. Group 162 is drawn to an antibody of SEQ ID NO: 2; Group 163 is drawn to an antibody of SEQ ID NO: 4.

4. The inventions listed as Groups 1-241 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical of Groups 1-80 is a purified human protein, whereas the special technical feature of Groups 81-160 is DNA fragments and expression vectors capable of expressing said DNA fragments, whereas the special technical feature of Group 161 is fluorescent protein-fused protein, whereas the special technical feature of Groups 162-241 is an antibody.

Groups 1-241 lack the same or corresponding special technical features because they are drawn to different products having different structures and functions. The proteins of Groups 1-80 and Group 161 are composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). Groups 1-80 and Group 161 have different structures as evidenced by the distinct sequence identifiers in Groups 1-80, and the lack of a specific structure of Group 161. Additionally, the protein of Group 161 comprises a fluorescing property when exposed to light, which yields a different excitation wavelength than that of the protein of Groups 1-80. The DNA of Groups 81-160 is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The antibodies of Groups 162-241 is composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Moreover, the products of Groups 1-241 can be used in materially different processes. For example, the DNA of Groups 81-160 can be used in hybridization assays, the antibodies of Groups 162-241 can be used in immunoassays, the protein

of Groups 1-80 can be used to make antibodies, and the protein of Group 161 can be used to determine the localization and expression patterns of proteins. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different, and therefore, lack the same or corresponding special technical features.

In addition, SEQ ID NOS: 1-160 and the antibodies against the SEQ ID NOS of Groups 1-80 lack the same or corresponding special technical features as each of the nucleic acids, proteins or antibodies differ in both structure and function, and therefore, do not relate to a single general inventive concept.

5. In Applicants' response of August 15, 2003, Applicants' elected Group II (claims 2-6 and 8), and SEQ ID NO: 1 (which encodes SEQ ID NO: 2). This corresponds with Group 81 above. Accordingly, claims 2-6 and 8, and SEQ ID NO: 1 has been examined on the merits.

Priority

6. Receipt is acknowledged of papers filed under 35 U.S.C. 119, which papers have been placed of record in the file.

Specification

7. Claims 2-6 and 8 are objected to for containing non-elected subject matter. Applicants should amend the claims to encompass only the elected subject matter (SEQ ID NO: 1). Furthermore, Claims 2 and 8 are objected to for depending from non-elected claims (e.g., 1 and 7). Appropriate correction is required.

8. The drawings refer to Figures 6-1, 10-1, 10-2 and 35-1; however, the specification does not refer to these drawings. These figures appear to be continuations of the sequence comparisons in Figures 6, 10 and 35, respectively. Applicants should amend the specification to refer to these Figures.

9. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 2-6 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

I. *The specification does not assert a specific utility because the utilities asserted by Applicants are general utilities that would be applicable to broad class of the invention.*

MPEP 2107.01 states:

> A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

Applicants alleged the following utilities:

- The protein provided by this application is useful for detecting the corresponding receptor or ligand as an intracellular targeting protein, for screening novel small molecule medicinals and so on, since each protein is considered to function within a cell.
- The protein is useful as an antigen for manufacturing the antibody against the proteins.
- The DNA fragment provided by this application is useful as a probe for gene diagnosis or as a gene source for gene therapy.
- The DNA fragment can be also used as a gene source for mass production of the protein.

(pg. 80, lines 13-21)

These utilities are not considered to be specific utilities for several reasons. First, the specification does not teach any specific receptors, ligands, or antigens that correspond with the protein. Additionally, as stated above, MPEP 2107.01 states "a claim to a polynucleotide whose use is disclosed simply as a gene probe" would not be considered to be specific in the absence of a disclosure of a specific DNA target". In the instant case, no specific DNA target is disclosed. Additionally, the utility of a gene source for gene therapy is not specific because any gene source could potentially be used in gene therapy, and furthermore, the specification has not disclosed any specific disease to be treated by gene therapy using the instant invention. Finally, the assertions that the proteins can be used to make antibodies and that the DNA fragment can be used as a gene source for "mass production" of the protein are not considered to be specific because these utilities are applicable to a general class of compounds, namely proteins and nucleic acids. Accordingly, the claimed invention is not supported by a specific utility.

II. *The specification does not assert a substantial utility because the utilities asserted by Applicants requires or constitutes carrying out further research to identify or reasonably confirm a "real world" use.*

MPEP 2107.01 states:

> A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities...the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition...

In the instant case, the alleged utilities summarized above do not define a "real world" use because the claimed invention can only be used for "basic research such as studying the properties of the claimed product itself *or the mechanisms in which the material is involved*" or for use in "a method of treating an unspecified disease or condition." (emphasis added) That is, the asserted utility of the claimed invention provides opportunities to detect or treat *unspecified* diseases, detecting unknown receptors, ligands, or for screening for unknown novel small molecule medicinals. At best, these utilities fall into the (A) and (B) categories listed above and require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

In *Brenner v. Manson*, 148 USPQ 696 (US SupCt 1966) the Court hold, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy."

In the instant case, the specification teaches SEQ ID NO: 1 is a *human* cDNA with an open reading frame, and that the protein encoded by SEQ ID NO: 1 (i.e., SEQ ID NO: 2) was

37.2% similar to a *bacterial* GTP-binding protein CgpA (*Caulobacter crescentus*), *except for the N-terminal region*. (emphasis added) (pgs. 20-21).

However, Applicants do not teach what this information is useful for. Applicants' assertion that SEQ ID NO: 2 is 37.2% homologous to a GTP-binding protein from *Caulobacter crescentus* (except for the N-terminal region) does not provide the skilled artisan with any information that would constitute a "real world" use. That is, the skilled artisan would have to prepare, isolate, and analyze the protein to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation on the protein itself would need to be required before it could be used. Accordingly, because one skilled in the art would need to carry out further research to identify or reasonably confirm a "real world" context of use, the claimed invention lacks a substantial utility.

III. *The specification is not supported by a well-established utility because one of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics on the invention.*

MPEP 2107 states:

> An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

Neither Applicants, nor the prior art have provided any evidence as to the function of the claimed invention; the utility is not specific or substantial, and it is not apparent as to how "a person of ordinary skill in the art would immediately appreciate why the invention is useful". For these reasons, the specification is not supported by a well-established utility.

Claim Rejections - 35 USC § 112 - Enablement

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 2-6 and 8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the specification is not enabling of using SEQ ID NO: 1 for the following reasons. There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue (see *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include, but are not limited to:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) ***Nature of the Invention & Breadth of the Claims***

The claims are drawn to a DNA fragment encoding SEQ ID NO: 2, the nucleic acid of SEQ ID NO: 1, vectors and host cells.

Thus, the claims encompass genomic DNA, which includes introns and regulatory sequences (e.g., promoters, enhancers, and any other regulatory elements).

(2) ***Relative Skill of those in the Art, State of the Prior Art, Amount of Direction or Guidance Presented & Presence or Absence of Working Examples***

The specification teaches SEQ ID NO: 1 is human cDNA with an open reading frame (pgs. 15, 20 and 21). The specification also teaches that in the protein encoded by SEQ ID NO: 1 (i.e., SEQ ID NO: 2) "there was found a similarity to bacteria GTP-binding protein CgpA (Accession No. AAC69623)" (pg. 20, lines 29-30). Specifically, the specification teaches in a comparison of SEQ ID NO: 1 and the *bacteria* GTP-binding protein CgpA (in Figure 1), "[o]ver the whole region, *except for the N-terminal region, they had a homology of 37.2%.*" (emphasis added) (pg. 21, lines 5-6). Finally, the specification teaches:

> [A]s result of reference to GenBank on the basis of the base sequence of clone 1 cDNA, those having a homology of not less than 90 % (e.g. Accession No. M429983) were found to have been registered in EST, but as it is of the partial sequence, *it cannot be decided whether or not the same protein as that encoded by clone 1 is encoded.*

(emphasis added) (pg. 21, lines 7-11).

The specification does not teach any examples of using SEQ ID NO: 1, but broadly states that "GTP-binding protein plays an important role in route of the intracellular signal transduction" (pg. 21, lines 12-13). Accordingly, the specification does not provide any guidance or teaching on how to use the claimed nucleic acids, and at best, teaches that "except for the N-terminal region" the claimed *human* cDNA of SEQ ID NO: 1 has a homology of only 37.2% with a *bacterial* GTP-binding protein CgpA.

Several findings with respect to the prior art and state of the art have been made. First, the bacterial GTP-binding protein CgpA (Accession No. AAC69623, from *Caulobacter crescentus*, enclosed herein) was made available on November 1st, 1998, and since then, a search of the art has not found any publications referencing or relating to this Accession Number. In a search for GTP-binding proteins of *Caulobacter crescentus*, the following articles teach the discovery, trial and error process and difficulties encountered by groups working on the GTP-binding protein of the *Caulobacter crescentus* gene (CgtA).

In 1997, Maddock et al. (J of Bacteriology 179(20): 6426-6431) identified the CgtA gene by carrying out significant molecular analysis, including isolation and characterization assays, such as antibody production and immunoblotting, as well as, testing CgtA protein levels during the cell cycle (pgs. 6428-9). Maddock concluded, "CgtA is a minor, yet essential protein found throughout the Caulobacter cell cycle". (pg. 6431, 1st column).

In 1999, Lin et al. (J of Bacteriology 181(18): 5825-5832) further characterized the CgtA protein, using binding assays, and concluded their study "demonstrated that the mechanism of regulation of CgtA is different from that of the well-characterized Ras-like GTP-binding proteins" (pg. 5831, 1st column). Additionally, Lin found "the role of the N-terminal extension is unknown", and "clearly, the challenge ahead is to determine the functional consequences of the CgtA-GTP-to-CgtA-GDP shift during *C. crescentus* growth." (pg. 5831, both columns).

In 2000, Lin et al. (FEBS Letters 484(1): 29-32), demonstrated "that although the N-terminus of CgtA is required for function in vivo, this domain plays no significant role in the guanine nucleotide binding, exchange or GTPas activity" (abstract). Lin also speculates on the N-terminus, questioning, "What might be the cellular role of the N-terminal domain?" and then

concludes, "It will be of interest to see if the N-terminal domain is necessary" for interaction with Rpl113 (see pg. 32, both columns).

In 2001, Lin et al. (Molecular Microbiology 39(4): 924-934) examined the functional consequences of altering amino acid residues within the putative effector-binding domain of CgtA (abstract). Specifically, Lin concluded that a substitution of T193 led to a protein incapable of functioning in vivo (pg. 925, 1st column and pg. 931, 1st column).

Over the four years of literature regarding the GTP-binding protein of the *Caulobacter crescentus* gene (CgtA) (which extends from before the filing to after the filing of the present application), the art has shown considerable amounts of experimentation in trying to determine the function and interaction of CgtA (a bacterial GTP-binding protein of *Caulobacter crescentus*). Specifically, significant questions remain about the N-terminus of CgtA, as well as, CgtA's interaction in cell growth. Additionally, the art has shown that even single amino acid changes can alter the function of CgtA, and therefore, certain critical amino acids required for in vivo function. Therefore, even after 4 years of research from the initial discovery of the GTP-binding protein of CgtA, substantial experimentation is still required.

In the present case, the specification and the art are silent as to any teachings regarding the function of *Caulobacter crescentus* GTP-binding protein CgpA. For example, the specification asserts the DNA fragment that encodes SEQ ID NO: 2 is 37.2% identical to the *Caulobacter crescentus* GTP-binding protein CgpA, not including the N-terminal region. In *Caulobacter crescentus* GTP-binding protein CgtA, the art specifically teaches the N-terminus is required for in vivo function, but has yet to be fully elucidated. However, in the instant case, the homology-based assertions have not taken the N-terminus into account, let alone carried out the

extensive research demonstrated by the prior art to characterize the *Caulobacter crescentus* GTP-binding protein CgtA. Consequently, the state of the art is high, whereas the guidance and direction given in the specification is very low.

(3) ***Quantity of Experimentation Necessary & the Unpredictability of the Art***

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. In *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art.

In the instant case, the specification, nor the prior art teaches how to use the claimed nucleic acids, and at best, teaches that "except for the N-terminal region" the claimed *human* cDNA of SEQ ID NO: 1 has a homology of only 37.2% with a *bacterial* GTP-binding protein CgpA. As discussed above, the prior art has shown the N-terminal region is necessary for in vivo function in other *Caulobacter crescentus* GTP-binding proteins, but yet the function of the N-terminal region has not been fully characterized. In the instant case, the specification is silent as to any function of the N-terminal region, nor does the specification specifically define what constitutes the N-terminal region, and finally, the N-terminal region is excluded when performing sequence comparisons. Accordingly, the lack of information regarding the N-terminus of the claimed invention does not teach the skilled artisan how the claimed invention functions and therefore, does not teach the skilled artisan how to use the claimed invention.

In order to carry out making and using of the claimed nucleic acids, the experimentation required by the skilled artisan would be considered undue. The skilled artisan would be required to carry out similar assays and experiments like those performed by groups working on *Caulobacter crescentus* GTP-binding protein CgtA (see above). As demonstrated by these teachings, such experimentation requires a large amount of trial and error analysis resulting in unpredictable outcomes (see above). In the instant case, the specification has provided the skilled artisan with little to no starting point for experimentation purposes. The specification asserts the claimed invention, a *human* cDNA encoding a protein, is minimally homologous to a *bacterial* protein. The prior art is silent as to any teachings regarding this bacterial protein, and the specification does not provide any guidance that would aid the skilled artisan in the function and ultimate use of the claimed invention. In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. However, "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Accordingly, in view of the unpredictability in the art and in view of the lack of specific disclosure in the specification, undue experimentation would be required to practice the invention as it is claimed.

Written Description

14. Claims 2, 5-6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 2 (and the depending claims thereof) is drawn to a DNA fragment encoding the protein of SEQ ID NO: 2. These claims broadly encompass genomic DNA, which includes introns and regulatory sequences (e.g., promoters, enhancers). However, the specification only teaches the cDNA of SEQ ID NO: 1.

The specification does not reasonably convey to one skilled in the art that Applicants were in possession of the claimed invention, because the specification does not describe the specific structures (e.g., promoters, enhancers), which are found in genomic DNA (i.e., the instant claims). More specifically, the specification only describes the cDNA encoding SEQ ID NO: 2, but not genomic DNA.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed* (See page 1117)." (emphasis added)

In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), at section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only one

member of the broadly claimed genus has been defined by structure, i.e., SEQ ID NO: 1. No genomic sequences flanking SEQ ID NO: 1 has been defined. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g., location of intron/exon boundaries, length of introns). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing, Applicants were in possession of the cDNA of SEQ ID NO: 1, Applicants were not in possession of the broadly claimed genomic DNA.

Applicant's attention is also drawn to the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1st Paragraph, Written Description Requirement" (published in Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111).

Accordingly, because the specification does make clear that Applicants were in possession of the claimed invention at the time the application was filed, and because the claims are broadly drawn to encompass genomic DNA, where the specification has only taught the cDNA, the claims lack adequate written description.

Conclusion

15. No claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806 or (571) 272-0788 after January 22, 2004. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199 or at (571) 272-0747 after January 13, 2004. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119 or at (571) 272-0782 after January 22, 2004. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
November 25, 2003

CARLA J. MYERS
PRIMARY EXAMINER